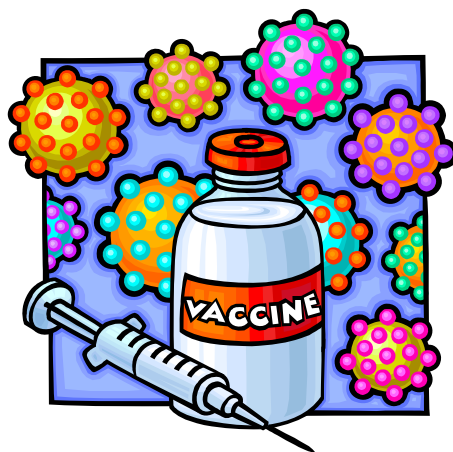


VACCINE MANAGEMENT PLAN



NORTH DAKOTA
DEPARTMENT *of* HEALTH

Division of Disease Control
October, 2005

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Introduction

Vaccine Storage and Handling is important in order to ensure the efficacy of vaccines in preventing vaccine-preventable diseases. Failure to store vaccines properly can lead to an inadequate immune response from the vaccines in children.

Storage and handling is also important in order to prevent the wastage of increasingly expensive vaccines. Last year in North Dakota, providers reported wasting 5,071 doses of vaccine, which is approximately \$97,237 worth of vaccine. This is only the reported wastage. There is no way to know how much vaccine was wasted and not reported.

Proper vaccine storage and handling is necessary in order to prevent having to repeat vaccinations in children that received improperly stored vaccine. Repeat vaccinations can lead to an increase in adverse reactions and wasted money spent on vaccinations that weren't needed.

It is important for providers to thoroughly read the North Dakota Vaccine Management Plan in order to prevent vaccine wastage in North Dakota.



Vaccine Ordering and Distribution

Vaccine Ordering

- Vaccine requests are accepted by the North Dakota Department of Health (NDDoH) by mail, FAX or electronic mail. Requests are not accepted by telephone. This is to ensure accuracy in filling provider requests. **(An example of a vaccine order form is shown in Appendix 1)**. Providers may also order vaccine online at: www.health.state.nd.us/disease/Immunization/OnlineOrdering/vacorder01.htm.
- Vaccine order forms should be filled out completely, including provider inventories. **The NDDoH will not send vaccine if the inventory portion of the form is not completed.**
- **Vaccine orders cannot be processed until the NDDoH has received a Monthly Doses Administered Report from the provider. (A Monthly Doses Administered Report can be found in Appendix 2).** Doses administered reports may also be obtained from the North Dakota Immunization Information System (NDIIS). Orders may be adjusted by the NDDoH if a provider has ordered too much vaccine based on provider inventory and doses administered reports.
- The NDDoH will process vaccine orders for providers within two weeks (weather permitting).
- Providers may only order enough vaccine to last one to two months.
- Providers may only order vaccine once a month.

- Providers should notify clinic staff when vaccine is being shipped to their clinic after they have ordered vaccine (especially staff receiving U.S. Mail daily). This is to prevent vaccine wastage.

Vaccine Distribution

- The North Dakota Immunization Program will act as the central depot for federal/state-funded vaccine.
- Vaccine is shipped on Mondays, Tuesdays, and Wednesdays only. This ensures the vaccine will arrive at the provider site before the weekend.
- The method of shipping vaccine in North Dakota is the U.S. Postal Service.
- Varicella vaccine is shipped directly to providers from the vaccine manufacturer.
- Vaccine will NOT be shipped on days when the daytime temperature is expected to be 90° F. or greater outside.
- Vaccine will NOT be shipped on days when the nighttime temperature is expected to be below 32° F.
- Vaccine shipments from the NDDoH are recorded in the NDIIS database, which includes the lot number, expiration date, doses sent and the provider to whom the vaccine is sent.
- The NDIIS will record and account for vaccine distributed to providers.



Receiving Vaccine

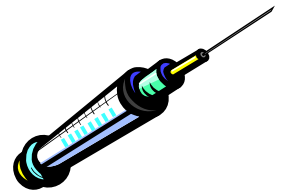
- It is the responsibility of the provider to arrange for someone to be available in your office to immediately receive and properly store the vaccine. This employee must be trained in proper vaccine storage and handling. A back-up employee should also be trained. The National Immunization Program created a Vaccine Storage and Handling Toolkit that is available online at <http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html>. The NDDoH recommends that all clinic staff involved in vaccine storage and handling view this toolkit online.
- It is highly recommended that providers have written protocols in place for receiving vaccine.
- Compare the vaccine received with the information on the invoice. Notify the Immunization Program **immediately** if there are any discrepancies in the order.
- All vaccines must be refrigerated immediately at 2-8° C (35-46° F).
- Varicella vaccine must be stored in the freezer, which maintains an average temperature of -15° C (+5°F).

Vaccine Handling, Storage & Disposal Guidelines

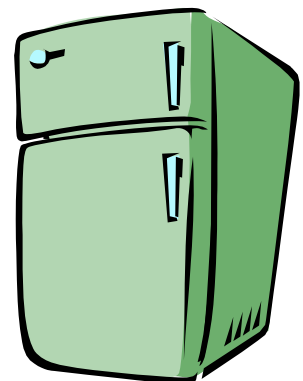
Providers must follow recommendations and general guidelines for handling, storage and disposal of vaccines from *Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals*, a publication from the U.S. Department of Health and Human Services (**See Appendix 3**). This guide is also available online at www.cdc.gov/nip/publications/vac_mgt_book.htm. Information in addition to these recommendations is listed below. These recommendations are NOT a substitute for the package insert included with each biological.

Vaccine Handling

- It is recommended that vaccines not be drawn up prior to administration.
- Biologicals may lose efficacy if stored in syringes for any period of time.
- If vaccines are drawn up prior to administration because of large clinics or limited staff, observe the following guidelines:
 - NO vaccine should be administered if drawn up in syringes for more than 8 hours.
 - NEVER return vaccine to a multiple dose container.
 - MMR may be kept up to 8 hours in a dark, cool place after reconstitution.
 - Varicella must be administered within 30 minutes after reconstitution. Discard reconstituted vaccine if not used within 30 minutes.
 - Properly stored vaccines are valid up until expiration date. If the expiration date is listed as a month and year only, vaccine is valid until the end of that month (e.g. July 98 -- valid until July 31, 1998).
Vaccines should be utilized until date expired.
 - Influenza vaccine expires the last day of June following the influenza season.



Vaccine



Storage

Refrigerated Vaccines

These biologicals **MUST** be stored at the recommended temperatures of 2°- 8° C (35°-46° F):

DT	Influenza
DTaP	IPV
DTaP/Hib	MCV-4
DTaP/HBV/IPV	MPV-4
HBIG	Td
Hepatitis A	Tdap
Hepatitis B	PCV-7
Hib	PPV-23

- The above vaccines must **NOT** be stored frozen.
- Vaccine diluents may be stored at room temperature.
- MMR vaccine may be stored in the refrigerator or the freezer. Storing MMR in the freezer prevents vaccine wastage due to power failures, because the vaccine will take longer to warm to out-of-range temperatures when frozen.

Frozen Vaccine

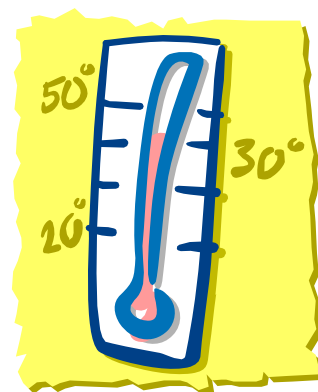
Varicella and MMRV:

- Varicella and MMRV vaccines are required to be stored at a temperature of 5° F (-15° C) or below.
- Discard reconstituted varicella vaccine after 30 minutes.

- Do not freeze reconstituted varicella vaccine.
- Protect varicella vaccine from light before and after reconstitution.
- Call 1-800-982-7482 to determine varicella vaccine efficacy if the above conditions are not met.

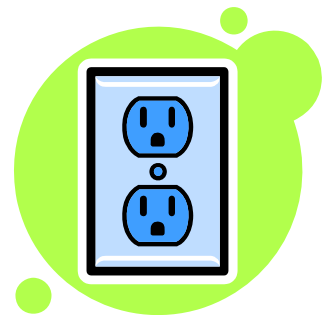
Providers must monitor the temperature of their refrigerator/freezer with thermometers and continuous temperature monitors.

- The optimal system for monitoring refrigerator/freezer temperatures is an automated temperature-sensing device. If a sensing device is not feasible, a maximum/minimum thermometer is recommended. Thermometers should be placed in the center of the refrigerator, next to the vaccine.
- Check temperature (preferably a maximum/minimum thermometer) on a regular basis (twice per day). Post a temperature-recording chart on your refrigerator/freezer to record the minimum and maximum temperatures. Copies of temperature recording charts should be sent in to the NDDoH at the end of every month. **(For temperature recording chart SFN 53775, see Appendix 4).**
- Temperature logs should be saved for a minimum of three years.
- Continuous temperature data loggers (HOBOS) will be sent to providers at the discretion of the NDDoH. HOBOS should be returned to the NDDoH once the clinic has received a replacement. **(See Appendix 5 for HOBO directions)**
- If refrigerator or freezer temperatures are out-of-range, record the temperature on a temperature log and isolate the affected vaccine and mark "do not use" until the vaccine manufacturers and the NDDoH have been contacted. Do not automatically assume that the vaccine is not viable.



- Do not store food or beverages in a refrigerator that contains biologicals.
- Stack vaccine with enough air space between stacks to allow cold air to circulate around the vaccine.
- Do not stack vaccine next to coils in the refrigerator. The coils are extremely cold and could result in the vaccine being ruined.
- Never store vaccine in the refrigerator door. Opening and closing vaccine doors in refrigerators causes unnecessary temperature changes and could cause vaccine failure.
- Once a month, check the vaccine inventory to ensure that expired vaccines are removed from the refrigerator. Contact the NDDoH if vaccine is expiring in a few months and the clinic will be unable to use the vaccine before expiration. The NDDoH will attempt to transfer the vaccine to another provider.
- Rotate biologicals in the refrigerator/freezer so that the shortest dated vaccine is used first.
- Place ice packs in the freezer and filled plastic water jugs in the refrigerator to help maintain temperature stability. This helps keep temperatures uniform and provides additional cold mass, both of which are useful, particularly if there is a power failure.
- Unofficial studies have indicated some biologicals will retain their potency when left at room temperature for short periods of time. Please contact the vaccine manufacturer for efficacy of vaccine not stored properly.

Other suggestions



- Install **PLUG GUARDS/PROTECTORS** in outlets. This helps prevent power loss.
- Protect and mark circuit breaker switches. This prevents interruption of power.
- A warning sign to not unplug the freezer/refrigerator by the plug/outlet may help to ensure that the freezer/refrigerator is not turned off (**See Appendix 6**).
- Lock storage facilities and equipment. This prevents unauthorized removal of vaccine and use of storage for other purposes.
- Diluent should be stored outside the refrigerator. It takes up space and does not need to be refrigerated.

Vaccine Return (outdated, frozen, etc.)

All unused, frozen, or expired vaccines should be returned to NDDoH:

Reason: NDDoH can receive an excise tax reimbursement for unused portions.

- A Vaccine Return Form should be completed for all wasted/unusable vaccines and sent to NDDoH (**See Appendix 7.**)

Vaccine Transfer

- A Vaccine Transfer Form should be completed and sent to the North Dakota Department of Health when vaccine is transferred from one clinic to another (**See Appendix 8**).

- Vaccine is transferred in the NDIIS from one provider's inventory to another once the form is received by the NDDoH.
- Cold chain procedures must be used during the transfer of vaccine.

Vaccine Disposal

Dispose of all materials properly:

- Syringes, needles, empty vials and material containing biologicals should be disposed in sharps containers, designated waste containers, etc. and burned, boiled or autoclaved before disposing in landfills.
- Other disposable items such as cotton balls, gauze, etc. should be secured in garbage bags for disposal.



Vaccine Packaging/Shipping

There are a variety of materials available to ensure that vaccines are protected and are kept at the appropriate temperature during shipment. Vaccines other than varicella need to be kept cool, but not frozen, during the shipping process. Varicella and MMRV, on the other hand, need to be kept frozen while being shipped.

- Varicella and MMRV vaccines must remain frozen during shipping. Use dry ice in block form to ship Varicella and MMRV vaccine. Do not handle the dry ice with your bare hands! Wear gloves while handling dry ice so you do not burn your hands. It is recommended to use no less than 5 lb. of dry ice per package.
- Do not ship vaccine if the daytime temperature is expected to exceed 90° F.

- Do not ship vaccine if the nighttime temperature is expected to be below 32° F. unless it is vaccine which should be frozen.
- Vaccines must stay adjacent to the cold packs in order to maintain the desired internal temperature range when the outside temperature is extremely high.
- Ensure vaccines during shipping are not going to freeze if the temperature outside is below 32° F. During the colder months, ensure vaccine is not placed directly on the freezer packs. Make sure the shipping box is well insulated to prevent freezing. Vaccines that are most susceptible to damage by freezing include DTaP and hepatitis B.
- When returning vaccine to the NDDoH, ship ONLY on Mondays, Tuesdays, or Wednesdays. This is to ensure vaccine will arrive at the site on a weekday.
- Consider outside temperatures when traveling with biologicals. Do not leave vaccine in a vehicle for extended periods of time in either very cold or very hot temperatures.

Appendix

1 Vaccine Order Form

- 2 Doses Administered Report
- 3 Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals
- 4 Temperature Log
- 5 HOBO Directions
- 6 "Do Not Unplug" Warning Signs
- 7 Vaccine Return Form
- 8 Vaccine Transfer Form

Request for Vaccine

Request for Vaccine		Completed by Provider		Completed by NDDoH	
		Doses Ordered	Doses on Hand	Doses Shipped	Lot Number Shipped
DTaP	10				
DTaP/HepB/IPV (Pediarix™) syringes	5				
DTaP/HepB/IPV (Pediarix™) vials	10				
Hepatitis A	10				
Hepatitis B	10				
Hib	10				
IPV	10				
MMR	10				
PCV-7 (Prevnar®)	5				
Pneumococcal Polysaccharide (for ages 2+)	5				
Td (adult)	15				
Varicella (shipped directly from manufacturer)	10				
Meningococcal Conjugate Vaccine (MCV-4) VFC only: Native American, Medicaid, No Health Insurance, Underinsured	5				
Tdap (tetanus, diphtheria and pertussis) VFC only: Native American, Medicaid, No Health Insurance, Underinsured	10				
HBIG*	1				
Hepatitis B TIP-LOK® pre-filled syringes**	25				
DT (pediatric)***	10				
Influenza****					

*Available to hospitals for peri-natal use only.

**Available to public health units only, needles not included.

***Contact ND Immunization Program at 800.472.2180. Order must be pre-approved over the phone.

****Seasonal, use separate Influenza Order Form.

1. Please limit vaccine orders to a **2-month supply**
3. Allow up to 2 weeks for delivery
4. Vaccine and materials are shipped on Mondays, Tuesdays, and Wednesdays (**weather permitting**)
5. Orders will not be filled until the NDDoH has received a **Vaccine Administration Monthly Report**

Ordered By:	
Date Ordered:	Requested Delivery Date (allow 2 weeks):
Telephone Number:	
Provider Number:	

Send To:

Facility:		
Attn:		
Address:		
City:	State:	Zip Code:

Request for Materials

Item	Quantity	Item	Quantity
CDC Vaccine Information Statements		Brochures	
Chickenpox Vaccine		A Guide to Vaccine-Preventable Diseases in Adults	
Diphtheria, Tetanus, and Pertussis (DTaP) Vaccines		A Parent's Guide to Vaccine-Preventable Diseases in Children	
<i>Haemophilus influenzae</i> type B (Hib) Vaccine		All Kids Need Hepatitis B Shots!	
Hepatitis A Vaccines		Guidelines for Vaccinating Pregnant Women	
Hepatitis B Vaccines		Hepatitis A Prevention	
Meningococcal Vaccine		If your children still haven't had chickenpox... they could be headed for greater risk	
MMR Vaccine		If You're Going to College This Fall (meningococcal brochure)	
Pneumococcal Conjugate Vaccine		Immunization of Adults (Your Call to Action)	
Pneumococcal Polysaccharide Vaccine		Immunization of Seniors (Your Call to Action)	
Polio Vaccine		Immunizations... Not Just Kids' Stuff	
Tetanus and Diphtheria Vaccine (Td)		Parents Guide to Childhood Immunization (Book)	
Camera-ready copy: (please circle)		Prevent Hepatitis B: Get Vaccinated!	
<div style="display: flex; justify-content: space-around;"> Inactivated Influenza Live Attenuated Influenza </div> <div style="display: flex; justify-content: space-around;"> Rabies Typhoid Yellow Fever </div>			
Miscellaneous		Questions parents ask about baby shots	
After the Shots... What to do if your child has discomfort		Tetanus – Are You at Risk?	
Build a Health Future Poster ↑ Large ↑ Small		What parents and caregivers need to know about pertussis	
Chickenpox Fact Sheet		State Forms	
Guide to Contraindications to Childhood Vaccinations		Adult Immunization Cards	
Health Record Folder with inserts		Adult Immunization History (SFN 52315) (Gold Sticker)	
Health Record Folder without inserts		Certificate of Immunization (SFN 16038)	
How to Protect Your Vaccine Supply (CD-Rom)		Childhood Immunization History (SFN 51756) (Blue Sticker)	
Immunizations for Babies (A Guide for Parents)		Official Document of Immunization (SFN 13895)	
Pertussis Fact Sheet		Request for Vaccine/Materials (SFN 13800)	
Recommended Adult Immunization Schedule		Temperature Log (SFN 53775)	
Recommended Childhood Immunization Schedule		Vaccine Administration Monthly Report (SFN 53774)	
Vaccinations for Adults You're NEVER too old to get shots!		Vaccine Administration Record (SFN 18385) ف 2 Part ف 3 Part	
Vaccine Adverse Events Reporting Form (VAERS)		Vaccine Administration Record (Series) (SFN 50922)	
Vaccine Information Statements What You Need to Know Booklet		Vaccine Transfer Form (SFN 53766)	
		Vaccine Return Form (SFN 53767)	

Ordered By:	
Date Ordered:	Requested Delivery Date (allow 2 weeks):
Telephone Number:	
Provider Number:	

SFN 13800 (Rev. 09/05)

Send To:

Facility:		
Attn:		
Address:		
City:	State:	Zip Code:

Vaccine Administration Monthly Report For All Providers

HEALTH AGENCY: _____
REPORT PERIOD (MONTH): _____
PERSON REPORTING: _____
PHONE: _____

Submission of this report is mandatory in order to request vaccine.
 No vaccine will be shipped until this report is on file at the State
 Health Department.

PROVIDER ID NUMBER _____

Number of doses of Vaccine Administered by Age Group															
Vaccine	< 1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44	45-64	65 +	Unknown	Total	Number of Doses in Current Inventory
DTaP															
DT (ped)															
Td															
Tdap															
DTaP/HepB/ IPV															
Hep A															
Hep B															
Hib															
IPV															
Meningococcal															
MMR															
Varicella															
PCV-7															
Influenza															
PPV-23															

- This report is due at the State Health Department before vaccine orders can be processed.
- Record each dose of vaccine given according to the type and the recipient's age.
- Total all age groups by antigen type and record.
- Record the number of doses of each antigen type that is in storage on the last day of the month under Current Inventory.
- This monthly report is mandated for documenting accountability of antigens purchased with public funds.
- Call 1.800.472.2180 with any questions.

North Dakota Department of Health
Immunization Program
 600 E. Boulevard Ave. Dept. 301
 Bismarck, ND 58505-0200
 Fax: 701-328.2499

VACCINE MANAGEMENT

Recommendations for Storage and Handling of Selected Biologicals

June 2005



Contents

DT, Td

DTaP, DTaP/Hib, DTaP/HepB/IPV

Tdap

HBIG

Hepatitis Vaccines: Hepatitis A, Hepatitis B, Hepatitis A/B, Hepatitis B/Hib

Hib

IPV

TIV

LAIV

MMR, MR, Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine

MCV4

MPSV4

PCV

PPV

Varicella (Chickenpox) Vaccine

DT: Diphtheria, Tetanus Toxoids—Pediatric Td: Tetanus, Diphtheria Toxoids—Adult

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until outdated, if not contaminated.

Special Instructions

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

**DTaP: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine—Pediatric**

**DTaP/Hib: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine Combined with *Haemophilus
influenzae* type b Conjugate Vaccine*—Pediatric**

**DTaP/HepB/IPV: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine, Hepatitis B Vaccine,
Inactivated Polio Vaccine—Pediatric**

**Tdap: Tetanus Toxoid, Diphtheria Toxoid,
Acellular Pertussis Vaccine—Adult**

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival**

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial, container, or manufacturer-filled syringe.

**Instructions for Reconstitution*
or Use**

Shake well before withdrawal and use. Do not use if resuspension does not occur with vigorous shaking.

**Shelf Life After Reconstitution*
or Opening**

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

* ActHIB® (sanofi pasteur) should be used within 24 hours of reconstitution if used alone. If sanofi pasteur DTaP is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. Sanofi pasteur DAPTACEL® is not licensed for use in reconstitution of ActHIB®.

** If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

HBIG: Hepatitis B Immune Globulin

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Reconstitution or Opening

Use until outdated, if not contaminated.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Hepatitis Vaccines: Hepatitis A, Hepatitis B, Hepatitis A/B, Hepatitis B/*Haemophilus influenzae* type b

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial, container or manufacturer-filled syringe.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Hib: *Haemophilus influenzae* type b Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution** or Use

Shake vial vigorously before withdrawal and use. Do not use if resuspension does not occur with vigorous shaking.

Shelf Life After Reconstitution** or Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first.

IPV: Inactivated Polio Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Multidose Vials: Shake vial vigorously before withdrawal and use. Withdraw 0.5 mL of vaccine into separate sterile needle and syringe for each immunization.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial. Doses remaining in the vial may be used until outdated if not contaminated.

Special Instructions

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

**ActHIB® (sanofi pasteur) should be used within 24 hours of reconstitution if used alone. If sanofi pasteur DTaP is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. Sanofi pasteur DAPTACEL® is not licensed for use in reconstitution of ActHIB®.

TIV: Trivalent Inactivated Influenza Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Formulated for use during current influenza season.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

Multidose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: Sterile until removal of hub cap.

Special Instructions

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements

Should be shipped frozen in insulated container with dry ice. at 4°F (-20°C) or colder. Shipment includes WarmMark™ temperature indicator.

Condition upon Arrival*

Should be frozen at 4°F (-20° C) or colder; **must not have thawed in shipment.** (All windows in WarmMark™ indicator should be white. If any indicator windows are red, do not use the product. Call the manufacturer for further instructions.)

Storage Requirements

Upon arrival, immediately store the vaccine in a freezer with its own exterior door. Must be maintained in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are permitted with this vaccine.** May be stored in either a manual defrost freezer or in a frost-free freezer compartment.

In order to maintain the temperature of 5°F (-15°C) or colder in the freezer, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperatures will be necessary to avoid freezing killed or inactivated vaccines.

NOTE: The manufacturer supplied freezer box is no longer required for storage of LAIV vaccine in a frost-free freezer. This new storage requirement applies to the 2005-2006 influenza season, not the 2004-2005 LAIV vaccine supply.

Shelf Life

Formulated for use during current influenza season.

Instructions for Use

Thaw sprayer in palm of hand before administering. Do not roll the vaccine sprayer in your hand, as this may dislodge the dose divider clip. May also be thawed in a refrigerator and stored at 35° to 46°F (2° to 8°C) for no more than 60 hours prior to use. **Do not refreeze after thawing.**

Shelf Life After Thawing

The vaccine should be administered shortly after thawing. Vaccine thawed in the refrigerator and stored at 35° to 46°F (2° to 8°C) that is not used within 60 hours must be discarded in an impenetrable sharps container.

Special Instructions

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

MMR: Measles/Mumps/Rubella Vaccine, MR: Measles/Rubella Vaccine, Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine

Shipping Requirements

Vaccine: Use insulated container. Must be shipped with refrigerant. Maintain at 50°F (10°C) or less. If shipped with dry ice, diluent must be shipped separately.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival*

Maintain at 50°F (10° C) or less. If above this temperature, see instructions (*) below.

Do not use warm vaccine. Refrigerate upon arrival.

Storage Requirements

Vaccine may be stored separately from diluent. Store as follows:

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). Protect from light at all times, since such exposure may inactivate the virus.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

NOTE: Freeze-dried (lyophilized) MMR vaccine may be maintained at freezer temperatures.

Shelf Life

Check expiration date on container or vial.

Instructions for Reconstitution and Use

Reconstitute just before using. Use only the diluent supplied to reconstitute the vaccine. Inject diluent into the vial of lyophilized vaccine and agitate to ensure thorough mixing. Withdraw entire contents into syringe and inject total volume of vaccine subcutaneously.

Shelf Life After Reconstitution, Thawing or Opening

After reconstitution, use immediately or store in a dark place at 35° to 46°F (2° to 8°C). **Discard if not used within 8 hours.**

Special Instructions

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

MCV4: Meningococcal Conjugate Vaccine, Groups A, C, Y, W-135

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures. Protect from light.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Follow manufacturer's directions.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first. Vaccine should be injected by the intramuscular route. Do not inject intradermally, subcutaneously, or intravenously.

MPSV4: Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W-135

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution and Use

Reconstitute gently. This is a white powder that yields a clear, colorless liquid when

reconstituted with 0.6 ml (single-dose vial) or 6 ml (10-dose vial) of sterile distilled water.

Shelf Life After Reconstitution or Opening

Single-Dose Vials: Use within 30 minutes of reconstitution.

Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used up to 35 days after reconstitution.

Special Instructions

Diluent to be used is sterile, distilled water for injection; diluent for 10-dose vial also contains 0.01% thimerosal. Reconstituted vaccine should be injected subcutaneously. Do not inject intradermally, intramuscularly, or intravenously.

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

PCV: Pneumococcal Conjugate Vaccine (7-Valent)

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Vaccine should appear as a homogenous white suspension after vigorous shaking. The vaccine should be administered intramuscularly only.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

This vaccine is a suspension containing adjuvant and should not be used if the particles cannot be resuspended after vigorous shaking.

Rotate stock so that the earliest dated material is used first.

PPV: Pneumococcal Polysaccharide Vaccine (Polyvalent)

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Follow manufacturer's directions.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until outdated, if not contaminated.

Special Instructions

Do not inject intravenously. Intradermal administration may cause severe local reactions and should be avoided.

Rotate stock so that the earliest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Vaccine: Use insulated container. Must be shipped with dry ice only, at 4°F (-20°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival*

Should be frozen. Vaccine should remain at 4°F (-20°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style" units are not appropriate for the storage of varicella vaccine.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on container or vial.

Instructions for Reconstitution and Use

Reconstitute just before using. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Protect from light. Discard if not used within **30 minutes** of reconstitution.

Special Instructions

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-609-4618 for a reevaluation of the product potency before using the vaccine.

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

* If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the [Quality Control office at the vaccine manufacturer](#); and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Manufacturer Quality Control Office Telephone Numbers

Manufacturer/Distributor	Telephone Number	Products
sanofi pasteur www.us.aventispasteur.com	800-822-2463	DTaP, DTaP-Hib, DT, Td, TT, Hib, MCV4, MPSV4, Influenza (TIV), IPV
Bayer Biological Products www.bayerbiologicalsusa.bayerhealthcare.com/products.asp	800-288-8371	IGIM, HBIG, TIG
Centers for Disease Control & Prevention Drug Service www.cdc.gov/ncidod/srp/drugs/drug-service.html	404-639-3670	Distributor for Diphtheria antitoxin
Chiron www.chiron.com/products/vaccines/index.html	800-200-4278 (medical information pharmacist) 800-244-7668 (customer support)	Influenza (TIV)
GlaxoSmithKline www.gsk.com/products/vaccines.jsp	866-475-8222 (customer support) 888-825-5249 (customer support)	DTaP, DTaP-HepB-IPV, HepA, HepB, HepA-HepB
Massachusetts Biological Labs	617-983-6400	Td, TT, IGIM, VZIG
MedImmune, Inc. www.medimmune.com	877-358-6478 (LAIV customer support) 877-633-4411 (general customer support)	Influenza (LAIV)
Merck www.merck.com	800-609-4618 (customer support) 800-672-6372 (customer support)	Hib, Hib-HepB, PPV23, HepA, HepB, MMR, Measles, Mumps, Rubella, Varicella
Nabi Biopharmaceuticals www.nabi.com	800-635-1766	HBIG
Wyeth www.wyeth.com	800-999-9384 (storage) 800-934-5556 (customer support) 800-666-7248 (customer support)	Hib, PCV7

Fahrenheit (°F) Temperature Log

Month:

REFRIGERATOR 35 - 46° F																	FREEZER ≤ 5° F										
Day of Month	Time	Staff Initials		≥49	48	47	46	45	44	43	42	41	40	39	38	37	36	35	34	33	≤32	≥8	7	6	5	4	≤3
1			am																								
1			pm																								
2			am																								
2			pm																								
3			am																								
3			pm																								
4			am																								
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14			am																								
14			pm																								
15			am																								
15			pm																								
16			am																								
16			pm																								

Instructions: Plan an "X" in the box that corresponds with the temperature (columns), day of the month, and am or pm (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes.

If the temperature is in the gray range: Store vaccine under proper conditions as quickly as possible, call the vaccine manufacturers to determine whether the potency of vaccine has been affected, and call the North Dakota Immunization Program at 1-800-472-2180. Document action on the back of this form.

HOBO Temperature Data Loggers

Instructions for Use

Introduction

In December 2003, the North Dakota Immunization Program made the decision to purchase HOBO data loggers to monitor the temperatures of refrigerators storing federal or state purchase vaccine. The data loggers will replace the Dickson Continuous Temperature Monitor. Once the provider has been set up to use the HOBO data logger, the provider may discontinue use of the Dickson Monitor. The North Dakota Immunization Program will not supply wheels or pens for the monitors. If the provider no longer wishes to keep the monitor, the monitor can be sent back to the Immunization Program. The provider may continue to use the monitor at their cost if they choose to do so.

How the HOBO Data Logger Works

The HOBO data logger records the temperature continuously in the refrigerator for a set period of time. The logger can be set up to record the temperature as often as necessary (i.e., every 5 seconds, every 1 minute, etc.). The data logger will help us to ensure that the vaccine is being stored properly, even during times when the clinic is closed or in the event of a power failure. After a period of time specified by the Immunization Program, the logger will be read and downloaded into a data base at the Immunization Program. Immunization Program staff will use the data to determine if there is a problem with the storage and handling of the vaccine.

General Instructions for clinic providers

1. Each provider will be assigned two data loggers that are labeled with their provider ID number. One data logger will be kept at the Immunization Program and one will be monitoring the temperature in the refrigerator at the provider site. The provider will only have one logger at a time.
2. The logger will be set up or "launched" by the staff at the Immunization Program. This requires special software purchased for this purpose; providers will not be provided with the software at this time.
3. During the "launching" of the logger, the battery will be checked, the interval for temperature readings will be set, and the logger will be initiated to start the reading. The logger can be set to read immediately, to start reading at a delayed time period or to start reading by button activation.
4. The logger will be sent to the provider either with a vaccine order or separately, depending on when the provider last ordered vaccine.

5. Upon receipt of the logger, the provider will place the logger in the refrigerator. If button activation is utilized, hold down the button on the front of logger for at least 3 seconds prior to placing the logger in the refrigerator. The logger is now ready to be placed in the refrigerator. The logger should be placed in the middle of the refrigerator next to the clinic thermometer. To be certain that the logger is working a red light will blink on the side of the logger. If the light is not blinking or you need assistance in placing the logger, please notify the Immunization Program. **The clinic will still be required to monitor and record temperatures of the vaccine in the refrigerator and/or freezer twice daily. Please remember that temperature logs must be kept at the clinic for a period of no less than three years.**
6. The clinic will be required to send the monitor back to the Immunization Program upon receipt of a new logger (usually this will be monthly). A self-addressed envelope will be provided. The clinic may also send the logger back in an empty vaccine cooler. Please notify the Immunization Program of you method for returning the logger.
7. Staff at the Immunization Program will then “read out” the logger and download the temperatures of the refrigerator for that month. The clinic will no longer be required to send in paper copies of the recorded temperatures.

If at anytime during the month a problem occurs in the refrigerator, please notify the Immunization Program immediately. Also, the Immunization Program must be notified in all cases of vaccine being stored at improper temperatures or if a power failure occurs.

Please call the Immunization Program at 701-328-3386 or 1-800-472-2180 for any questions or concerns that you may have about the data loggers.

Heather Weaver, Director, Immunization Program

Molly Sander, Surveillance Coordinator, Immunization Program

North Dakota Department of Health

Division of Disease Control

600 E Boulevard Ave. Dept. 301

Bismarck, North Dakota 58505-0220

Instructions: To activate, push button on front of monitor for three seconds. Red light will begin to blink. Then place monitor in refrigerator.

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

Refrigerator Contains Vaccines!



DO NOT UNPLUG!



VACCINE RETURN FORM

NORTH DAKOTA DEPARTMENT OF HEALTH (NDDoH)

SFN 53767 (Rev. 06/05)

All vaccine received through the NDVFC program that has become nonviable (i.e., expired or spoiled) must be returned to the North Dakota Department of Health. NDDoH does not receive replacement vaccine but does receive credit for the federal excise tax that was applied to each dose.

Remove expired or spoiled vaccine from the refrigerator or freezer immediately. Mark the vaccine as nonviable to avoid unintentional use. No special storage is required at this point.

Return Vaccine to:

North Dakota Department of Health
Immunization Program
600 East Boulevard Ave.
Bismarck, ND 58505.0200
Fax Number: 701.328.2499

1. Complete this form when returning vaccines.
2. **If returning usable vaccine:** call us and we will inform you on how to proceed.
3. **If returning unusable vaccine** select the most efficient method.
Packing on ice is not necessary.

Contact the North Dakota Department of Health at 701.328.3386 or 800.472.2180 with any questions or concerns.

Provider ID Number: _____

Date: _____

Provider Name: _____

Street Address: _____ City: _____ Zip Code: _____

Contact Person: _____

Phone: _____

Please select reason for returning unusable vaccine:

1. Vaccine expired ☐

2. Proper temperature not maintained due to:

Refrigerator/freezer failure ☐

Power failure ☐

Refrigerator/freezer unplugged ☐

Other (describe) _____

3. Unusable upon delivery ☐

4. Other (describe) _____

Please select reason for returning usable vaccine:

1. Nearing expiration date ☐

2. No longer using this vaccine ☐

3. Ordered too much of the vaccine ☐

4. Wrong vaccine received ☐

5. Wrong vaccine ordered ☐

6. Provider closing ☐

7. Other (describe) _____

Vaccine	Lot Number	Number of Doses
DT		
DTaP		
DTaP/HepB/IPV		
DTaP/HIB		
HepA		
HepB		
HIB		
IPV		
Influenza		
MCV-4		
MMR		
PCV-7		
PPV		
Td		
Tdap		
Varicella		



VACCINE TRANSFER FORM
NORTH DAKOTA DEPARTMENT OF HEALTH (NDDoH)
SFN 53766 (Rev. 06/05)

Transferring Provider

Provider ID Number: _____

Date: _____

Transferring Provider Name: _____

Street Address: _____ City: _____ Zip Code: _____

Contact Person: _____ Telephone No.: _____

Return this form to:

North Dakota Department of Health
Immunization Program
600 East Boulevard Ave
Bismarck, ND 58505-0200
Fax Number: 701.328.2499

1. Complete this form when transferring vaccine.
2. Maintain proper vaccine temperature during transfer.

Vaccine	Receiving Provider Name	Receiving Provider ID Number	Lot Number	Number of Doses
DT				
DTaP				
DTaP/HepB/IPV				
DTap/HIB				
HepA				
HepB				
HIB				
IPV				
Influenza				
MCV-4				
MMR				
PCV-7				
PPV				
Td				
Tdap				
Varicella				

Reason for Transfer: _____

Contact the North Dakota Department of Health with any questions or concerns at
701.328.3386 or 800.472.2180

MEMO

TO: Prevention Partnership Providers
Local Public Health Units

FROM: Molly Sander
Immunization Surveillance Coordinator

RE: North Dakota Vaccine Management Plan

DATE: October 13, 2005

Enclosed is the North Dakota Department of Health (NDDoH) Vaccine Management Plan. The NDDoH Immunization Program recommends that all employees that are involved in vaccine ordering, handling, and storage read this manual.

Please contact the NDDoH Immunization Program with any questions or concerns.

Enclosure.